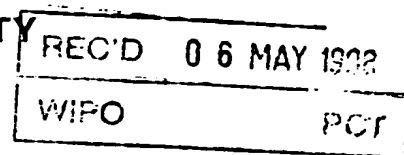


PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)





Applicant's or agent's file reference 5454-01-EMA	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (PCT/IPEA/416)	
International application No. PCT/US97/12390	International filing date (day/month/year) 16/07/1997	Priority date (day/month/year) 24/07/1996
International Patent Classification (IPC) or national classification and IPC A61K31/195		
Applicant WARNER-LAMBERT COMPANY et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 4 sheets, including this cover sheet.  
  
☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☒ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand  07/02/1998	Date of completion of this report  04.05.98
Name and mailing address of the IPEA/   European Patent Office D-80298 Munich Tel. (+49-89) 2399-0. Tx: 523656 epmu d Fax: (+49-89) 2399-4465	Authorized officer  Engl. B  Telephone No. (+49-89) 2399-8283  

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. PCT/US97/12390

**I. Basis of the report**

1. This report has been drawn on the basis of (*substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.*):

**Description, pages:**

1-13 as originally filed

**Claims, No.:**

1-15 as originally filed

**Drawings, sheets:**

1/18-18/18 as originally filed

2. The amendments have resulted in the cancellation of:

- ☐ the description, pages:  
☐ the claims, Nos.:  
☐ the drawings, sheets:

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

4. Additional observations, if necessary:

**see separate sheet**

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. PCT/US97/12390

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. Statement**

Novelty (N)	Yes:	Claims	1-15
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-15
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	
	No:	Claims	see item I.4

**2. Citations and explanations**

**see separate sheet**

**VI. Certain documents cited**

**1. Certain published documents (Rule 70.10)**

and / or

**2. Non-written disclosures (Rule 70.9)**

**see separate sheet**

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT - SEPARATE SHEET**

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International application No. PCT/US97/12390

**Concerning Section I.4**

Claims directed to methods of treatment of the human or animal body by therapy might be found inadmissible in some patent systems.

**Concerning Section V**

Subject to what is stated below, methods of treating pain using compounds of formula I as claimed is neither taught nor suggested in the prior art available. Novelty and inventive step (Article 33 (2) and (3) PCT) can therefore be acknowledged.

**Concerning Section VI**

No check as to whether the present priority has been validly claimed has been made. Therefore, the document D1: Br. J. Pharmacol. 121 (8):1513-1522 (1997) cited in the International Search Report could become relevant for the assessment of novelty and inventive step.

## PCT

## INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference <b>5454-41-EMA</b>	<b>FOR FURTHER ACTION</b> see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
International application No. <b>PCT/US 97/ 12390</b>	International filing date (day/month/year) <b>16/07/1997</b>	(Earliest) Priority Date (day/month/year) <b>24/07/1996</b>
Applicant <b>WARNER-LAMBERT COMPANY et al.</b>		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 3 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. ☐ Certain claims were found unsearchable (see Box I).
2. ☐ Unity of invention is lacking (see Box II).
3. ☐ The international application contains disclosure of a **nucleotide and/or amino acid sequence listing** and the international search was carried out on the basis of the sequence listing
  - ☐ filed with the international application.
  - ☐ furnished by the applicant separately from the international application,
    - ☐ but not accompanied by a statement to the effect that it did not include matter going beyond the disclosure in the international application as filed.
  - ☐ Transcribed by this Authority
4. With regard to the **title**, ☒ the text is approved as submitted by the applicant  
☐ the text has been established by this Authority to read as follows:
5. With regard to the **abstract**, ☒ the text is approved as submitted by the applicant  
☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this International Search Report, submit comments to this Authority.
6. The figure of the **drawings** to be published with the abstract is:  
 Figure No.            ☐ as suggested by the applicant. ☒ None of the figures.  
☐ because the applicant failed to suggest a figure.  
☐ because this figure better characterizes the invention.

# INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 97/12390

**A. CLASSIFICATION OF SUBJECT MATTER**  
IPC 6 A61K31/195

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	G.A. MELLICK ET AL.: "Gabapentin in the management of reflex Sympathetic Dystrophy." J. PAIN SYMPTOM. MANAGEMENT, vol. 10, no. 4, 1995, pages 265-266, XP002043783 see the whole document ---	1, 14
P, X	G.A. MELLICK ET AL.: "Reflex sympathetic dystrophy treated with gabapentin." ARCH. PHYS. MED. REHABIL., vol. 78, no. 1, 1997, pages 98-105, XP002043784 see the whole document --- -/--	1, 14

☒ Further documents are listed in the continuation of box C.

☐ Patent family members are listed in annex.

\* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

4 November 1997

Date of mailing of the international search report

24/11/1997

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentiaan 2  
NL - 2280 HV Rijswijk  
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,  
Fax: (+31-70) 340-3016

Authorized officer.

Klaver, T

# INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 97/12390

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P, X	<p>M.J. FIELD ET AL.: "Gabapentin and S-(+)-3-isobutylgaba represent a novel class of selective antihyperalgesic agents."</p> <p>BR. J. PHARMACOL., vol. 121, no. 8, 1997, pages 1513-1522, XP002043785 see the whole document</p> <p>-----</p>	1-15

PATENT COOPERATION TREATY

PCT

## NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

United States Patent and Trademark  
Office  
(Box PCT)  
Crystal Plaza 2  
Washington, DC 20231  
ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 24 February 1998 (24.02.98)	
International application No. PCT/US97/12390	Applicant's or agent's file reference 5454-41-EMA
International filing date (day/month/year) 16 July 1997 (16.07.97)	Priority date (day/month/year) 24 July 1996 (24.07.96)
Applicant SINGH, Lakhbir	

1. The designated Office is hereby notified of its election made:



in the demand filed with the International Preliminary Examining Authority on:

07 February 1998 (07.02.98)



in a notice effecting later election filed with the International Bureau on:

2. The election ☒ was

was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO  
34, chemin des Colombettes  
1211 Geneva 20, Switzerland

Facsimile No.: (41-22) 740.14.35

Authorized officer

H. Zhou

Telephone No.: (41-22) 338.83.38